Biotechnology Industry Organization
1225 Eye Street NW, Suite 400
Washington, DC 20006

May 10, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20857

Re: Docket No. 2004D-0042, Federal Register February 10, 2004 (Volume 69, Number 27), Pages 6308-6309, Draft Guidance for Industry on Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) submits the following comments in response to the Food and Drug Administration's (FDA's) notice regarding publication of the draft Guidance for Industry, "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" (the Draft Guidance). In the Draft Guidance, the agency states that certain communications from the manufacturer of drug or biological products to consumers and health care practitioners about disease awareness would not be subject to the requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA regulations. The stated goal of the Draft Guidance is to promote the education and awareness of disease conditions, which in turn would improve the diagnosis and treatment of patients, especially those with under-diagnosed and under-treated conditions.

BIO is the largest trade organization serving and representing the biotechnology industry. With more than 1,000 worldwide members, BIO is committed to representing the interests of large and small biotechnology companies, academic institutions, and research institutions that develop biotechnology products. As a leading voice in the biotechnology industry, BIO strongly supports FDA's effort to promote disease awareness communications and agrees that these types of communications can help improve diagnosis and treatment of certain diseases and health conditions. Finally, we believe that the Draft Guidance is a positive step toward facilitating

FDA's Strategic Action Plan initiatives to improve consumer health through better information and to advance patient safety. Therefore, we strongly support FDA's effort to develop the Draft Guidance and to publish it for comments.

BIO is concerned, however, that under the Draft Guidance disease awareness communications may be considered labeling or advertising in instances where the communication is sponsored by biotechnology firms that manufacture only one product or that manufacture the only commercially available therapeutic product for a particular disease or health condition. As discussed below, this characterization could potentially affect a significant number of biotechnology companies – particularly smaller or start-up companies – and could frustrate the agency's stated goal of increasing awareness of under-diagnosed and under-treated conditions. Further, it would be inconsistent with FDA's broader long-standing policy of promoting the development of treatments for serious and life-threatening conditions and unmet medical needs.

COMMENTS

1. For diseases or conditions where there is only one, one leading, or few available treatments, or where the manufacturer has only a single product, FDA's proposed exceptions will defeat the goals of the Draft Guidance.

The Draft Guidance encourages the development of disease awareness communications, particularly for "serious or life-threatening diseases or health conditions that are under-diagnosed or under-treated" (lines 158-159). FDA believes that these types of educational awareness programs can be "effective tools for disseminating information to consumers and health care practitioners about untreated and inadequately treated health conditions" and that "there is clear evidence that such promotion can increase treatment rates" (FDA Press Release, New FDA Draft Guidances Aim to Improve Health Information (Feb. 4, 2004). Under certain conditions, "[t]his kind of communication constitutes neither labeling nor advertising and is, therefore, not subject to the requirements for the disclosure of risk information and other requirements under the [FDCA]" (lines 109-111). These conditions include consumer- and practitioner-directed communications that promote the awareness, diagnosis, and treatment of particular diseases but do not identify a particular drug or include a "representation or suggestion relating to a particular drug" (line 107).

BIO strongly agrees with these statements and supports the agency's efforts to adopt them as principles underlying labeling policy. BIO is concerned, however, that the Draft Guidance carves out two exceptions that are both directly relevant to many biotechnology companies and that have the potential to severely frustrate FDA's policy goals:

> Where a company is the *only* manufacturer of a commercially available medical product for a particular disease or health condition or where a company *only* manufactures one product, that company is not automatically disqualified from disseminating communications that discuss a disease or health condition relating to that product. (lines 118-121, emphasis added)

FDA then limits this policy:

> If, however, FDA determines that a supposed disease awareness communication impliedly identifies a particular drug or device, which may be the case when a communication relates to a drug or device that is the only drug or device in its diagnostic or therapeutic class or the only product manufactured by a company, then the agency may treat the communication as labeling or advertising under the [FDCA]. (lines 121-125, footnote omitted)

According to the agency, "the mere appearance of the company's name in conjunction with a disease reference could trigger the [FDCA's] advertising or labeling requirements, depending on the overall meaning and context of the communication" (footnote 4).

BIO is concerned that these limitations will have two unintended and negative consequences. First, they potentially single out small firms that have only one or a handful of approved products. Second, they stand in potential juxtaposition to decades of agency policies that encourage the development of products in areas of unmet medical need.

a. Many Biotechnology Companies Market Only One Approved Product or Only a Few Approved Products

Among BIO's members are many small biotechnology companies that manufacture only one product or manufacture the leading commercially available treatment for a condition. Years of innovative research have produced biotechnology products representing new and improved treatment for health conditions, including previously unmet medical needs. In fact, it is biotechnology's valuable contribution to the advancement of public health that prompted former FDA Commissioner Mark McClellan to state that "the potential medical benefit of biotechnology is the main reason why most medical experts believe that the most important innovations are still ahead of us - as new scientific insights from genomics, proteomics, information technology and other emerging fields are increasingly translating into better health and better lives for patients throughout the country and the world" (Speech by former FDA Commissioner Mark B. McClellan before BIO, June 23, 2003, available at http://www.bio.org/events/2003/media/mcclellan_0623.asp).

As written, however, the Draft Guidance would make it virtually impossible for small, emerging biotechnology companies to generally counsel practitioners and educate consumers about serious or life-threatening health conditions without triggering the labeling or advertising requirements. According to the agency, if a disease awareness communication "impliedly identifies" (line 122) a drug, the communication may be deemed labeling or advertising and subject to certain regulatory requirements. However, this limitation threatens to eviscerate the guidance for many BIO members.

For example, if a BIO Member were to develop a treatment of chronic angina – a condition that affects millions for which no new therapy has been introduced in more than 20 years – but had no other approved product, consumers could be denied important disease awareness information. Similarly, several BIO members are working to develop new biotechnology-derived therapies to tackle diabetes. If a company with no other approved products receives approval before the

others, is it unable to conduct (without risk disclosure and other regulatory requirements) a communication campaign about a disease that the agency has expressly identified as one which could benefit from increased disease awareness (*see* lines 28-30, in which FDA identifies diabetes as an under-diagnosed, under-treated health condition)? In short, no company should be precluded from important disease awareness activities because the company only markets one product or happens to market a product that is the only available therapy for a particular disease. In that circumstance, BIO asks FDA to take the opportunity to widely spread information about the available treatment – regardless of the identity of the manufacturer.

b. FDA Has Long Encouraged Innovation in Areas of Unmet Medical Need and Should Craft the Draft Guidance Accordingly

The effect of the Draft Guidance could be contrary to its stated policy goal of encouraging consumer- and practitioner-directed disease awareness communications where serious or life-threatening diseases are concerned. Further, it would be contrary to FDA's broader initiatives over the last decade to improve medical innovation, "especially in emerging areas or those of great medical need" (McClellan Speech before BIO, *op. cit.*). The development of treatments for serious or life-threatening conditions that address unmet medical needs has been a long-term priority for the agency:

- In 1988, FDA promulgated investigational new drug ("IND") regulations to "expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely debilitating illnesses, especially where no satisfactory alternative therapy exists." 21 CFR 312.80; *see generally,* 21 CFR Part 312, Subpart E.

- FDA established procedures in 1992 to accelerate the approval of new drug or biologic products that treated serious or life-threatening illnesses and that provided "meaningful therapeutic benefit" over existing treatments. 21 CFR 314.500; 21 CFR 601.40; *see generally,* 21 CFR 314, Subpart H; 21 CFR 601, Subpart E.

- Congress mandated the development of a fast track approval program to accelerate the review of treatments for serious or life-threatening conditions that address unmet medical needs. *See* 21 USC 356; Food and Drug Administration Modernization Act of 1997 § 112(b); *see also* Guidance for Industry, Fast Track Drug Development Programs – Designation, Development, and Application Review (Sept. 1998).

- Priority review is available for biologic products that significantly improve the safety or effectiveness of the treatment, diagnosis, or prevention of serious or life-threatening diseases. *See* CBER Manual of Standard Operating Procedures and Policies 8405 (Aug. 8, 2003).

Under these programs, many new and innovative products have been developed and approved for serious or life-threatening conditions and critical, unmet medical needs, including biotechnology products manufactured by or licensed to BIO members. *See, e.g.,* http://www.fda.gov/cder/rdmt/internetftap.htm and http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm. These policies and programs are important to FDA's mission of advancing public health and promoting access to accurate

information that will improve the public's health (as stated in FDA's Mission Statement at http://www.fda.gov/opacom/morechoices/mission.html).

Consistent with these important policy goals, BIO asks that FDA refrain from excluding these products from the scope of the Draft Guidance simply because the product may be the only available treatment for a condition. Instead, BIO suggests that FDA take the opportunity to increase awareness about such therapies through disease-awareness communication. In addition, BIO asks FDA to refrain from further thwarting these long-standing policy goals by limiting the use of disease awareness communications when the only approved drug therapy is also the only product of a particular manufacturer. FDA would be sending the wrong message to the public and industry in those circumstances where single-product companies receive fast track designation to speed approval of a product but are later denied the opportunity to increase public awareness of that product.

Therefore, BIO requests FDA to delete these exceptions to the agency's proposed help-seeking and disease awareness communications policy. Alternatively, we propose that FDA change "or" to "and" in its description of the exception at line 124: "diagnostic or therapeutic class *and* the only product manufactured by a company." With this simple change, the majority of BIO members' communications in this area would fall within the parameters of the draft guidance.

2. FDA should provide additional examples of the type of practitioner-directed disease awareness communications that would not be considered advertising or labeling.

The Draft Guidance provides two examples of manufacturer communications that would fall outside the scope of FDA's labeling and advertising regulations (lines 135-141): 1) recommendations for screening and treatment of diseases or health conditions in primary care settings, and 2) practitioner-directed counseling recommendations for particular diseases or health conditions. BIO accepts these examples and applauds FDA's inclusion of them. BIO would like to make clear that the guidance should not be narrowly applied by the agency in the future. There are additional circumstances under which manufacturers can undertake disease awareness communications. For instance, companies developing therapies for diseases that are difficult to diagnose may develop practitioner-oriented communication to facilitate enrollment in clinical trials. BIO requests FDA to take steps to assure that the listed examples are considered only as examples during future implementation of the guidance.

CONCLUSION

In summary, BIO supports FDA's policy of allowing industry-developed help-seeking and disease awareness communications to consumers and practitioners. We agree with FDA that this type of communication can play an important role in helping consumers recognize symptoms and seek help for otherwise under-treated conditions. Disease awareness communications directed to practitioners can also improve the diagnosis and treatment of such conditions. Further, BIO applauds FDA's recognition of single-product manufacturers or conditions where there is only one, one leading, or few available treatments. In these circumstances, however, we believe that FDA's proposed policy will unduly limit communication about important diseases simply because of the small size of many biotechnology companies. Therefore, we urge the agency to withdraw the proposed exceptions to this otherwise laudable policy.

We thank the agency for considering our comments and look forward to future collaboration on this important topic.

Sincerely,

Sara Radcliffe
Director, Science Policy
Biotechnology Industry Organization